

December 8, 1999

The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD. 20852

To Whom It May Concern:

As a corneal surgeon that has obtained tissue for almost two decades for my patients from the Florida Lions Eye Bank (FLEB), an eye bank supported by more than 6,000 Lions in this state, I feel I must express my opposition to the proposed FDA legislation requiring donor medical history interviews for corneal donors taken under state law at medical examiners. This legislation would require unnecessary and time-consuming screening. The time it would take to locate and interview the next-of-kin would take away from the length of time a cornea is viable for transplant, if we could locate the next of kin at all in a timely manner. The supply of transplantable corneas would become dangerously low and extend the suffering and impaired vision of thousands of Floridians. If this additional screening could insure that corneal tissue did not come from a donor having a communicable disease, I would agree the additional step was necessary. However, our many extremely credible medical advisors believe that the screening would not improve the prevention of communicable disease transmission. This is due in part to the fact that next-of-kin or others most often do not have complete knowledge of the donor's past medical, sexual, and social history. Also, someone who might have CJD in the latent stage would not exhibit any symptoms!

The Florida Lions Eye Bank has operated efficiently and effectively since the passage of FL Statue 732.99185, mostly due to co-operation of South Florida Medical Examiners. In fact, between July 1977 and July 1999, FLEB has retrieved, screened, and provided more than 28,000 corneas totally free of charge. Approximately 900 corneas alone were obtained from the Broward and Dade County Medical Examiners in 1998. During this time, there has never been any evidence of transmission of Creutzfeld Jakob Disease (CJD) to a single recipient. Dr. Joseph H. Davis, Retired Director of the Miami-Dade County Medical Examiners Department states that the "ME donor pool has better quality control standards than the hospitalized chronically ill elderly pool". The FLEB firmly agrees with his opinion.

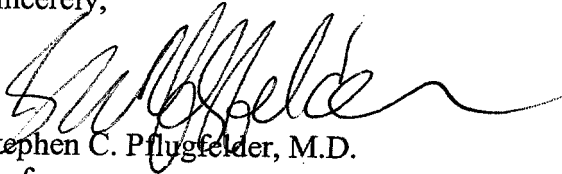
This legislation profoundly needs to be reassessed, as it will have numerous negative affects on the public's well being. In South Florida, this eye bank will be forced into charging for our services, thus costing Medicare over a million dollars each year. More importantly the Florida Lions Eye Bank will not be able to serve hundreds of corneally blind patients each year. Until there is a proven blood test to detect CJD, the FDA cannot insure that any donor does not harbor the disease simply by requiring a donor medical history interview.

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Please eliminate this requirement from the proposed regulation.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Pflugfelder", with a long, sweeping horizontal line extending to the right.

Stephen C. Pflugfelder, M.D.
Professor

Cc: Senators Bob Graham, Connie Mack
Representatives Charles T. Canady, Dan Miller, Porter J. Goss, Dave Weldon, Mark
Foley, Carrie Meek, Ileana Ros-Lehtinen, Robert Wexler, Peter Deutsch, Lincoln Diaz-
Balart, E. Clay Shaw, Jr., Alcee Hastings

C. Pflugfelder, M.D.

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